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Sent via Fax

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No: 2002N-0273 (formerly Docket No. 02N-0273)

Substances Prohibited From Use in Animal Food and Feed

Dear Sir or Madam,

Bovine products and byproducts are used for both food and pharmaceuticals. These human uses require the highest level of safety. Because of the hardy nature of the prion and its high potential for cross contamination, the most effective way to protect bovine products and bovine derived materials from contamination by BSE is to ensure that infected animals or carcasses never enter processing plants. The goal would be to discover and remove infected animals from production as early as possible in the infection and long before they would be sent to slaughter to prevent any exposure to susceptible animals. The exemptions in the current ban, as well as in the newly proposed rule, make this difficult if not impossible, as there are still legal avenues for ruminants to consume potentially contaminated ruminant protein.

It is our opinion that the proposed rule falls woefully short of being able to prohibit potential exposure. In fact, by the FDA's own statement, the exempted tissues, which are known to have infectivity (e.g., distal ileum, DRGs, etc.), would cumulatively amount to approximately 10% of the infectivity in an infected animal. Thus, the proposed rule still allows the possibility for cattle to be exposed to BSE through the following:

1. Feeding of materials currently subject to legal exemptions from the ban (e.g., poultry litter, plate waste)
2. Cross feeding (the feeding of non-ruminant rations to ruminants) on farms
3. Cross contamination of ruminant and non-ruminant feed

In addition, we have other concerns. There are other species that are susceptible to BSE, and the current regulations allow for SRMs to be included in feed for these animals.

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We also feel that the FDA has not taken recent research results into consideration. These findings have considerable bearing on the proposed rules and should be incorporated into policy. Our laboratory would be willing to discuss these findings with the FDA or submit a summary paper for your use.

With best wishes,

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